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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,583	06/25/2003	Kai Y. Xu	P72864US0	5808

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
07/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,583	XU, KAI Y.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 7-38* is/are pending in the application.

4a) Of the above claim(s) *8-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2009 has been entered.

   Claims 1, 3, 4 and 7 have been amended.

   Claims 2, 5, 6 have been canceled.

   Claims 1, 3, 4 and 7-38 are pending.

   Claims 1, 3, 4 and 7 are under examination.

2. This Office Action is in response to applicant's submission filed May 6, 2009.

   The previous rejections of record can be found in the Office Action mailed January 7, 2009.

   The previous rejection under 35 U.S.C. § 112, 1st paragraph, written description has been withdrawn in view of applicant's amendment to the claims and applicant's arguments.

   The previous rejection under 35 U.S.C. § 112, 2nd paragraph has been withdrawn in view of applicant's amendment to the claims and applicant's arguments.

   The previous rejection under 35 U.S.C. § 112, 1st paragraph, enablement has been withdrawn in view of applicant's amendment to the claims and applicant's arguments.

   The previous rejection under 35 U.S.C. § 102(b) has been withdrawn in view of applicant's amendment to the claims.

   New Grounds of Rejection are put forth below.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

   > The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter Rejection.

Claim 1 recites "wherein the binding of the Jianye-2 antibody...increases...(Na^++K^+)-ATPase enzyme activity."

The phrase "wherein the binding of the Jianye-2 antibody...increases...(Na^++K^+)-ATPase enzyme activity" represents a departure from the specification and the claims as originally filed.

The specification does not appear to provide blazemarks nor direction for "wherein the binding of the Jianye-2 antibody...increases...(Na^++K^+)-ATPase enzyme activity." Such a limitation recited in the instant claim, which did not appear in the specification as filed, introduces a new concept and violates the description requirement of the first paragraph of 35 U.S.C. 112.

In particular, according to the instant specification Jianye-2 antibody enhances rat heart cell contraction without inhibiting (Na^++K^+)-ATPase activity. (see page 19, 3rd paragraph; page 43, 1st paragraph and Figure 2). In contrast, the instant specification does not mention the possibility of Jianye-2 antibody increasing (Na^++K^+)-ATPase enzyme activity.

Applicant is required to cancel the new matter in the response to this Office action.

Alternatively, applicant should indicate in detail how the instant specification provides written support for the claimed limitation. See MPEP 714.02 and 2163.06.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "A therapeutically effective composition comprising: an isolated and purified antibody (Jianye-2), which is specifically made against the synthetic amino acid sequence, RSATEEEPPNDD (SEQ ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEQ ID NO: 1)…wherein the binding of the Jianye-2 antibody to the amino acid sequence, RSATEEEPPNDD (SEQ ID NO: 1)…"

Claim 4 recites "The therapeutically effective composition of claim 1, wherein the amino acid sequence RSATEEEPPNDD (SE0 ID NO: 1) is an antigen or a component of a vaccine,

and the antibody is a polyclonal antibody, a monoclonal antibody, a humanized antibody or a human antibody."

The issue is that it is unclear from the disclosure of the specification if "Jianye-2" is a name given to ***any*** antibody, be it polyclonal, monoclonal or humanized that "is specifically made against the synthetic amino acid sequence, RSATEEEPPNDD (SEQ ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEQ ID NO: 1)…" as recited in claim 1 OR if "Jianye-2" is a name given to **BOTH *any*** antibody be it polyclonal, monoclonal or humanized etc. ***AND*** a ***particular*** monoclonal antibody having ***particular variable and constant domain sequences***.

The primary reason for this uncertainty is because the instant specification exemplifies production of a polyclonal antibody against SEQ ID NO: 1 which is refers to simply as "Jianye". However, the remainder of the specification describes a number of experiments where "the Jianye-2 antibody" was characterized by a variety of measures.

Moreover, the specification describes at page 24, 1st paragraph the production of a humanized version of the Jianye-2 antibody where "***The donor monoclonal*** antibodies of the present invention Jianye-2 or KX-1 antibodies, which are specific for the rat α-subunit of (Na^++K^+)-ATPase i.e., RSATEEEPPNDD and DVEDSYGQQWTYEQR peptides respectively." Note that humanized antibodies are typically prepared from a particular donor monoclonal antibody having particular variable and constant domain sequences.

Furthermore, while not always the case, it is customary in the antibody art that when an antibody is referred to by a laboratory designation, e.g., "the OKT3 antibody" or "the HAT antibody" or "the cA2 antibody" this designation refers to a particular antibody having particular variable and constant domain sequences.

Additionally with further reference to claim 4 which recites "The therapeutically effective composition of claim 1, wherein the amino acid sequence RSATEEEPPNDD (SE0 ID NO: 1) is an antigen or a component of a vaccine, and the antibody is a polyclonal...," it is unclear if the claim is drawn to a composition comprising at least two parts, the first part being the amino acid sequence RSATEEEPPNDD (SE0 ID NO: 1) **in the form of** an antigen or **in the form of** a component of a vaccine ***AND*** a second part, the second part being the antibody which can be polyclonal etc. ***OR*** if the claim is drawn to a composition comprising an antibody which can be polyclonal etc. and the "wherein the amino acid sequence RSATEEEPPNDD (SE0 ID NO: 1) is an antigen or a component of a vaccine" merely further defines the origin of SEQ ID NO: 1 against which/to which the claimed antibody was produced/binds.

Additionally, claim 7 recites "the therapeutically effective composition of claim 4, wherein the antibody or antigen or vaccine is administered to a patient in an effective therapeutic amount…" Given the ambiguity of claim 4, the meaning of claim 7 is so ambiguous as to defy further analysis.

Thus, the instant claims fail to particularly point out and distinctly set forth the subject matter which applicant regards as the invention, and as a consequence the metes and bounds of the claimed invention are so unclear as to preclude the skilled artisan from ascertaining what would infringe the instantly claimed invention should it issue as a patent.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As a preliminary matter, it is noted that this rejection is contingent on one interpretation of the instant claims. In particular, if "Jianye-2" refers to both any antibody be it polyclonal, monoclonal or humanized etc. and a particular monoclonal antibody having particular variable and constant domain sequences which is one option put forth in Section 6 above, then it is apparent that the particular Jianye-2 monoclonal antibody having particular variable and constant domain sequences is required to practice the claimed invention.

As a required element, the "Jianye-2" antibody must be known and readily available to the public or obtainable by a repeatable method set forth in the specification.

Neither the instant record nor the prior art indicate the "Jianye-2" antibody was known and readily available to the public, and the antibody is not obtainable by a repeatable method set forth in the specification.

A deposit of the cell line(s) which produces the "Jianye-2" antibody may satisfy the enablement requirement of 35 USC 112, 1st paragraph. See 37 CFR 1.801-1.809 as well as MPEP § 2400.

For example, if a deposit of a cell line producing the antibody has already been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the cell line which produces the claimed antibody has been deposited under the Budapest Treaty and that the hybridoma *will be irrevocably and without restriction or condition released to the public upon the issuance of a patent* would satisfy the deposit requirement made herein. See 37 CFR 1.808.

Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806.

If the antibody is deposited after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line that produces the claimed antibody(ies) described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

9. No claim is allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachary Skelding/
Examiner, Art Unit 1644